DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 21, 2014

FUJIFILM Medical Systems U.S.A., Inc.
% Ms. Katherine Choi
Regulatory Affairs Lead
419 West Avenue
STAMFORD CT 06902

Re: K142003
Trade/Device Name: FDR D-EVO II Flat Panel Detector System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 22, 2014
Received: July 23, 2014

Dear Ms. Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use (IFU) Statement

FDR D-EVO II Flat Panel Detector System (DR-ID1200)

This Section contains:

Indications for Use Statement

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142003

Device Name

FDR D-EVO II Flat Panel Detector System (DR-ID1200)

Indications for Use *(Describe)*

The Wireless/Wired FDR D-EVO II flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO II is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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FUJIFILM
Fujifilm Medical Systems, USA

510(k) Summary

FDR D-EVO II Flat Panel Detector System (DR-ID1200)

Date: September 18, 2014

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

Contact Person:

Name: Katherine Y. Choi, RAC
Title: Regulatory Affairs Lead
Telephone: (203) 602-3568
Facsimile: (203) 602-3785

Identification of the Device:

Proprietary/Trade Name:	FDR D-EVO II Flat Panel Detector System (DR-ID1200)
Classification Name:	Stationary x-ray system
Regulations Number:	21 CFR 892.1680
Product Codes:	90 MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector System

Identification of the Legally Marketed Device:

FDR D-EVO Flat Panel Detector System (DR-ID600), K132509 cleared 11/25/2013

I. DEVICE DESCRIPTION

Fujifilm's FDR D-EVO II Flat Panel Detector System (DR-ID1200) is a portable digital detector system that interfaces with, and acquires and digitizes x-ray exposures from, standard radiographic systems. The FDR D-EVO II is designed to be used in any environment that would typically use a radiographic cassette for examinations of adults, pediatrics and neonates. The detector models support both wireless and wired/tethered data communication between the detector and the system. Detectors can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid or free cassette exams.

While maintaining Fujifilm's unique Irradiated Side Sampling (ISS) design delivering high image quality, FDR D-EVO II offers the new and improved 1200 series flat panel detectors with upgraded wireless feature, memory exposure mode, and extended image readout feature. Additionally, the 1200 series detectors are equipped with several changes: Rounded-edge design for easy handling, image compression algorithm for faster image transfer, improved internal circuit design for electronic noise reduction, new

LED design for easy detector identification, extra protection against ingress of water, and antibacterial coating designed to maintain cleanness. Not only the 1200 series detectors' robust design enhances load-bearing characteristics, but also the power-saving designs combined with the new battery packs and charger improve battery performance. The weight of 1200 series detectors is less than that of 600 series.

II. INDICATIONS FOR USE

The Wireless/Wired FDR D-EVO II flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO II is not intended for mammography, fluoroscopy, tomography, and angiography applications.

III. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Fujifilm's FDR D-EVO II FPD System (DR-ID1200) has the same Indications for Use as the predicate device (K132509). FDR D-EVO II detectors' scintillator materials (GOS or CsI), indirect conversion method (a-Si), Fujifilm's unique ISS technology, readout properties, 150µm pixel pitch, and 16 bit-depth remain the same as the predicate device (K132509). The MTF and DQE measurements are very similar between FDR D-EVO II and the predicate device (K132509). While both FDR D-EVO II and the predicate device (K132509) are equipped with wireless detectors, wireless feature in FDR D-EVO II has been improved by expanding operating frequency options, and adding new wireless components. FDR D-EVO II's system configurations are very similar to the predicate (K132509), but a later version of FDX Console will support FDR D-EVO II. Additionally, active area size and pixel matrix of the FDR D-EVO II detectors are slightly different from the predicate device (K132509). FDR D-EVO II detectors weight less, but can withstand heavier loads when compared to the predicate device (K132509). Other differences includes, as aforementioned, new memory exposure mode, extended image readout feature (up to 10 sec), image compression algorithm, increased IPX level, antibacterial coating, and power-saving designs, all of which have been successfully tested and validated.

IV. SUBSTANTIAL EQUIVALENCE

Fujifilm FDR D-EVO II FPD System (DR-ID1200) is substantially equivalent to the following legally marketed device.

Legally Marketed Device	510(k) #	Clearance Date
FDR D-EVO Flat Panel Detector System (DR-ID600)	K132509	11/25/2013

Both FDR D-EVO II (DR-ID1200) and FDR D-EVO (DR-ID600) are portable digital detector systems that are used to acquire x-ray exposures. The new FDR D-EVO II has the same Indications for Use, and very similar functional and technical requirements as the currently-cleared predicate device, K132509. The most detector characteristics remain unchanged for FDR D-EVO II, and the image quality is substantially equivalent to the predicate device. The design modifications made for the FDR D-EVO II have been successfully tested and validated as summarized below.

V. SUMMARY OF STUDIES

Non-clinical Performance Data: FDR D-EVO II FPD System (DR-ID1200) conforms to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 62366, IEC 62494-1 and DICOM. In addition, the FDA's *Guidance for*

the Submission of 510(k)'s for Solid State X-ray Imaging Devices (issued on August 6, 1999) was followed to describe the detector characteristics, and *Radio Frequency Wireless Technology in Medical Devices* (issued on August 14, 2013) was followed to test the changes in wireless features. As required by the risk analysis, necessary verification and validation activities were performed. For example, software changes related to design modifications such as memory exposure mode, extended image readout feature, image compression algorithm, and battery power-saving designs were successfully evaluated according to the FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (*issued on May 11, 2005) based on a moderate level of concern. Load-bearing characteristics and enhanced protection against ingress of water were tested and passed. The internal circuit design change to achieve noise reduction was demonstrated through EMC emission testing per IEC60601-1-2, and the results were satisfactory. Antibacterial coating's safety and effectiveness were demonstrated through ISO 10993 testing, and JIS Z 2801 (equivalent to ISO 22196) testing. Furthermore, the image quality evaluation confirmed that the image quality of the FDR D-EVO II system using new 1200 series detectors is substantially equivalent to that of the predicate device.

Clinical Performance Data: No clinical study has been performed. The substantial equivalence has been demonstrated by non-clinical studies.

VI. CONCLUSION

Based upon the supporting data summarized above, we concluded the next generation FDR D-EVO II Flat Panel Detector System (DR-ID1200) is as safe and effective as the legally marketed device DR-ID600 (K132509), and do not raise different questions of safety and effectiveness than K132509.